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SYMPOSIUM: CLINICAL RISK AND JUDICIAL REASONING

The Regulation of Medical Malpractice in Japan

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Abstract How Japanese legal and social institutions handle medical errors is little known outside Japan. For almost all of the 20th century, a paternalistic paradigm prevailed. Characteristics of the legal environment affecting Japanese medicine included few attorneys handling medical cases, low litigation rates, long delays, predictable damage awards, and low-cost malpractice insurance. However, transparency principles have gained traction and public concern over medical errors has intensified. Recent legal developments include courts' adoption of a less deferential standard of informed consent; increases in the numbers of malpractice claims and of practicing attorneys; more efficient claims handling by specialist judges and speedier trials; and highly publicized criminal prosecutions of medical personnel. The health ministry is undertaking a noteworthy "model project" to enlist impartial specialists in investigation and analysis of possible iatrogenic hospital deaths to regain public trust in medicine's capacity to assess its mistakes honestly and to improve patient safety and has proposed a nationwide peer review system based on the project's methods.

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Introduction

How Japanese legal and social institutions handle medical errors is little known outside Japan. This article, drawing on extensive in-country research, including interviews with judges, attorneys, and physicians, analyzes the interaction between Japanese medicine and the law to highlight areas of commonalty and uniqueness in comparison with treatment of medical error in the United States and other Western societies.

The article first sets out the major background features of Japanese health care that affect law. It then examines features of Japanese law that have affected health care, including the small number of private attorneys, low litigation rates, delay in case resolution, predictable damage awards, and low-cost malpractice insurance. The article notes important recent legal developments affecting medical practice, including the advance of informed consent theory, more efficient handling of medical malpractice claims, a surge of new attorneys entering practice, and an emphasis on criminal law as a forum for accountability for medical error. The article concludes by describing a current initiative to improve review of iatrogenic adverse events—the health ministry's "Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths"—and the ministry's proposal to adapt and expand the project's review system to a nationwide scale.

Features of Japanese Health Care Affecting Law

Health care in Japan is provided on a price-controlled, fee-for-service basis. Since 1961, all legal residents (including noncitizens) have been covered by national health insurance [1, 7]. The percentage of the GDP allocated to health

care in 2004 was 8%, compared with 15.2% in the United States and 7.4% to 11.5% in other Western nations [33]. This relative efficiency in provision of care has not entailed any substantial sacrifice in technology advancement; the level of technology in top Japanese hospitals parallels practices worldwide. Japanese longevity is among the world's best, and infant mortality statistics are excellent [34]. Much credit for these achievements goes to health-promoting lifestyle factors, but the healthcare system contributes as well [1].

Traditionally, with respect to physician-patient relationships, a paternalistic paradigm prevailed in Japan. The creed of medieval Japan's feudal lords in ruling their subjects—"Keep them ignorant and dependent"—was often ironically applied to doctors' methods of managing patients [31]. Customary practice hid cancer diagnoses from patients, withheld information about prescription drugs, refused access to their medical records, and sometimes conditioned provision of medical treatment on waiver of the right to sue or complain [19].

However, principles of transparency have gained traction in Japan since the 1990s following a scandal of HIV-contaminated blood transfusions [3] and enactment of freedom of information [17] and medical records access measures [18]. Recently, coverups of medical error at hospitals of high repute received front page coverage in Japanese media, and public distrust of the previously sacrosanct medical profession has become a topic of national concern [21].

The Japanese healthcare establishment stood ill-prepared to address this public questioning. Institutional structures to monitor quality of care have been weak. Professional licensure and discipline authority, exercised by the Ministry of Health, Labor, and Welfare, seldom inquired into failures of medical safety. Peer review was the exception, not the rule. Few hospitals conducted morbidity and mortality conferences. Medical education's hierarchical structure discouraged questioning of practices taught by revered professors with control over employment placements, even when those practices were unsupported by good empiric data [1]. The hospital accreditation system has fostered improvement only marginally; a voluntary accreditation system does exist, but accreditation is unnecessary to qualify for reimbursement for procedures performed or drugs prescribed. Less than one-third (2523 of 8832) of hospitals are accredited [9], and in any case, accreditation criteria do not address compliance with standards of evidence-based medicine or honesty with patients about adverse events. Physicians can advertise specialty expertise and practice in specialty fields without specialty certification [6]. These weaknesses in professional accountability structures have channeled public attention toward legal institutions regulating medical quality.

Features of Japanese Law Affecting Health Care

The substantive content of Japanese law affecting civil claims for medical malpractice—cases in which patients or families seek monetary compensation for harms allegedly caused by failure to meet the professional standard of care—is, on the whole, similar to the content of medical malpractice law in the United States, Canada, Western Europe, and Australia. Spectators at malpractice trials in those nations, or fly-on-the-wall observers of settlement negotiations between experienced attorneys for plaintiffs and defendants, would recognize a broad similarity in the arguments about what standard of care physicians are held to and about whether departure from that standard caused the patient any harm.

The most noteworthy differences between regulation of medical quality in Japan and elsewhere stem not from the standards applied, but rather from particular aspects of the way the Japanese legal system works. These characteristics include a small number of private attorneys working in the field, low litigation rates (at least by US standards), delay in case resolution (at least before recent reforms), structured and predictable damage awards, uniformly cheap malpractice insurance for physicians, and an unusual emphasis on criminal law to regulate poor-quality medical care.

The number of practicing attorneys in Japan (24,300 [11] with a population of approximately 127 million, or one attorney for every 522 persons) is far less than in the United States (548,000 [44] with a population of 301 million, or one for every 55 persons). The Japanese legal profession is also more exclusive; the passage rate for Japan's bar examination, until a recent relaxation of standards, ranged from 1.7% to 3.4% from the 1970s through the 1990s, compared with 63% to 70% in the United States from 1997 to 2006 [30, 36]. Few Japanese attorneys specialize in medical cases, particularly away from major metropolitan areas, one reason for the relative infrequency of malpractice litigation. Malpractice cases filed in court, which ranged from 200 to 400 nationwide in the 1970s and 1980s, began increasing substantially in the 1990s, and in 2004 peaked at 1110 before a recent decline [43] (Fig. 1). (These figures exclude claims settled informally outside the judicial realm, a number that experienced attorneys say far exceeds the number of cases filed in court [39].) Despite this recent increase, the overall number of malpractice claims annually per million patients, in court and out of court, is considerably higher in the United States (an estimated 50,000 to 60,000 claims for a total population of 301 million, or 170–200 per million) [24] than in Japan (perhaps 5000 to 10,000 claims for a total population of 127 million, or 40–80 per million). Rates of preventable adverse events as estimated from large-scale reviews of

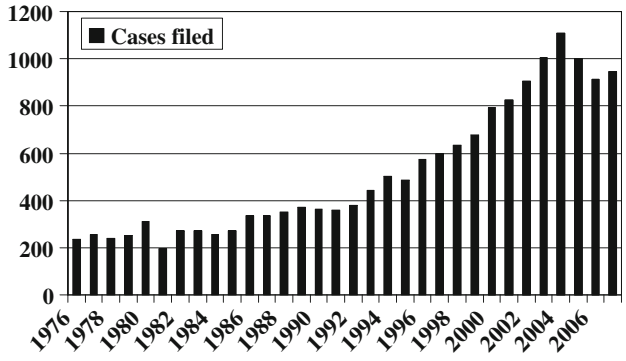

Fig. 1 Japanese medical malpractice civil cases filed in court increased from 1976 to 2007. (Source: Supreme Court of Japan, Administrative Office.)

randomly selected medical records in the United States and Japan are roughly comparable [16, 38]. Thus, the reservoir of potentially valid but unfiled claims, vast in the United States [23, 42], is likely even larger on a population-adjusted basis in Japan [20].

One set of reasons for the relatively few claims and malpractice law specialists in Japan is economic; both patients and plaintiffs' lawyers confront a less favorable reward structure than in the United States. American plaintiffs' attorneys operate on a pure contingency fee basis, so patients with strong cases but limited financial resources can obtain representation without the obstacle of a substantial initial payment. Japanese patients, by contrast, must pay a substantial up-front retainer to the attorney and a filing fee to the court based on the amount claimed, which together typically amount to the yen-equivalent of several thousand dollars [4]. Furthermore, the US attorney's standard contingency fee typically starts at one-third of the ultimate recovery (if any) plus expenses with the percentage increasing if the case goes to trial and appeal. In Japan, traditionally, the attorney's fee has been limited to the retainer plus 10% to 15% of the amount collected from the defendants with various adjustments [10]. This difference in plaintiff attorney rewards creates a difference in attorneys' case screening philosophies. A case involving high preparation expense, uncertain chance of success, but large potential damages might be accepted by a US plaintiff's firm but refused by one in Japan, both making decisions in accordance with rational calculations of probable returns to the firm.

A second reason for the scarcity of malpractice actions has been delay in case resolution. In Japan, like in most nations other than the United States, cases are presented to judges rather than juries. Hearings are spaced out over months or even years rather than concentrated in a single trial. A panel of three judges determines the facts, decides whether medical personnel were negligent and whether any negligence was the cause of harm, and assesses the patient's injury. Before recent reforms, medical trial proceedings tended to be protracted with a mean duration from filing to resolution of 3½ years in 1994 and some notorious cases lasting more than 20 years [35]. Medical cases were proverbially likened to rain in June: "One never knows when it will end." These delays discouraged the filing of even meritorious cases and engendered public criticism of the quality of the judiciary's handling of medical claims.

In assessing damages, judges typically refer to a schedule of awards used in traffic accident cases. The range of discretion in setting the amount of damages is far less than that afforded American juries under headings such as "pain and suffering." Thus, knowing the nature of a patient's injury, experienced Japanese attorneys can estimate with considerable accuracy the likely award if the defendant is found negligent. This predictability of damages aids pretrial settlement of cases [37]. So does the practice of many judges of privately discussing with attorneys the judges' tentative views of the strengths or weaknesses of their cases, effectively informing each side's negotiating positions between trial sessions. Occasionally, settlement negotiations are complicated by patients' insistence on apologies, which many physicians are loath to give.

Like in the United States, expert testimony is critically important; but in addition to experts testifying for plaintiffs and defendants, Japanese judges often select experts who are not beholden to either party. On the whole, taking into account the judicial process described and its results, Japanese physicians appear to be less skeptical of the judicial system's ability to arrive at results acceptable to them than are most of their US counterparts.

Malpractice liability premiums in Japan are lower and more stable than in the United States. Premiums in Japan do not vary depending on the physician's specialty or geographic area of practice [28]. In effect, there is a nationwide risk pool for all physicians in private practice, covered by the Japan Medical Association (JMA) indemnity insurance system, and the relatively few doctors in high-risk specialties are subsidized by the majority in low-risk practices. Although increases in medical litigation have recently inflicted losses on the JMA system and forced premium hikes, the rates for individual physicians are still moderate by US standards; annual premiums climbed in 2003 from only ¥55,000 (US $500) prevalent in the 1990s to only ¥70,000 (US $640) [8, 22]. Premiums for hospitals, too, are moderate: roughly ¥30,000 (US $270) per bed per year. Most physicians are hospital employees, rather than private practitioners, and their potential civil liability is in effect covered by these hospital-paid premiums.

Recent Changes in Litigation Affecting Medicine

Several recent legal developments have affected the interface between Japanese physicians and the judicial system, heightening external scrutiny of the medical profession. These developments include courts' adoption of a less deferential standard of informed consent; reforms in judicial handling of medical malpractice claims with specialist judges and speedier trials; liberalization of bar admission standards; and more pronounced involvement of the criminal justice system in disciplining errant practitioners.

Regarding informed consent, Japanese courts historically deferred to physicians' discretion, upholding, for example, customary nondisclosure to patients with cancer diagnoses [13]. However, courts have recently adopted a more robust conception of informed consent, reflecting stronger concern for individual rights and greater social transparency [19]. The Supreme Court, for example, departing from paternalist precedent, in 2000 upheld the claim of a Jehovah's Witness given an emergency transfusion during hepatic cancer surgery despite her previously expressed contrary preference. From a medical standpoint, the outcome was successful; the patient survived more than 5 years, surpassing preoperative expectations. Nevertheless, the court held that the patient's rights had been violated and awarded a symbolic sum of damages [15], an outcome resembling contemporary decisions by US courts [5]. These cases have spurred physicians to better communication of accurate medical information to patients.

A second arena for reform concerns procedures for adjudicating medical cases. Once disparaged for long delays and arcane procedures, courts have become more user-friendly. One important initiative is the establishment in eight urban areas of special court divisions to which all medical malpractice cases are assigned. Judges in these divisions acquire experience on medical issues and build working relationships with medical specialty societies from which they draw expert witnesses, unaffiliated with either party, in prompt fashion. Some courts have also instituted a system of consulting "expert commissioners" from the medical profession at the issue-sorting stage of a case to improve focus and efficiency.

These initiatives have dramatically increased the speed of courts' handling of medical malpractice cases. In 1994, the mean duration of malpractice cases from filing to final disposition was 41.4 months, more than four times the mean duration of all civil cases. By 2007, however, the mean duration of malpractice cases was reduced to 23.6 months nationwide [43] and in the Osaka district court's medical division to a mere 14.7 months [29]. Few US jurisdictions can match the Osaka court's business-like celerity. These improvements are likely to make it less burdensome for injured patients to engage the court system.

Moreover, the once narrow gates of entry to the legal profession have opened considerably, the result of a new government policy of making legal services more widely available. The bar examination pass rate in 2007 was 40%, compared with the 1.7% to 3.4% rate typical of the last half of the 20th century, and 2400 newly minted attorneys entered practice, a 10% increase in the number of lawyers in a single year [12]. The impact of these new cohorts of attorneys on the incidence of medical malpractice litigation will be gradual, because it takes time to gain the expertise required in such a demanding practice. However, few doubt that in the long term, pressures on hospitals and physicians from civil malpractice litigation are likely to intensify.

In the sphere of criminal rather than civil law, Japan has taken a more publicly rigorous stance toward medical error than has the United States or other nations with a common law heritage such as Canada and the United Kingdom. A series of highly publicized cases of error at major medical institutions beginning in 1999 resulted in prosecutions and often convictions of physicians, nurses, and hospital administrators. The prosecutions proceeded on three grounds: (1) professional negligence causing death or injury, a crime under Japan's Criminal Code; (2) alterations of patients' charts, indictable as interference with evidence; and (3) failure to report "unnatural deaths" to police within 24 hours, violating a provision of the Medical Practitioners' Law that the Supreme Court has interpreted as requiring reports of deaths potentially resulting from medical error [22].

The most notorious case of failure to report an "unnatural death" arose from a patient's death at Tokyo's Hirō Hospital in 1999 after injection of what a nurse thought was a heparin solution. The syringe, left on the cart by another nurse, contained a toxic disinfectant. After a hospital committee decision, the hospital CEO ordered the death certificate falsified and sent no notification to police for 11 days. The Supreme Court affirmed the hospital CEO's conviction for violating the requirement of timely police notification, rejecting his contention that the requirement violated the constitutional privilege against self-incrimination [14]. The nurses were also convicted of professional negligence.

The Supreme Court's 2004 decision sent a tsunami across the medical profession. Doctors had not generally considered iatrogenic deaths to be "unnatural." These deaths were not reported to police or to any public or professional entity, and families were frequently deceived about their causes. The Hirō Hospital case and other medical prosecutions for coverups after errors symbolized, to the Japanese public, medicine's secretive, self-protective

nature. Alarmed by this public reaction, but lacking any legal definition of which hospital deaths are "unnatural" and therefore reportable, various medical specialty organizations issued contradictory recommendations. The prestigious Science Council of Japan acknowledged the importance of transparency in medicine but called for a limited reporting scheme; deaths clearly the result of medical negligence should be immediately notifiable, but ambiguous cases should first be reviewed by experts [41]. Hospital administrators were whipsawed between distaste for disruptive police investigations if they reported a borderline case and fear of prosecution if they did not. Physicians' concerns intensified in 2006 when police in Fukushima Prefecture led an obstetrician out of the hospital in handcuffs on belatedly learning of the 2004 death of one of his patients after a difficult cesarean section delivery [32]. (The physician was acquitted in a closely watched decision in August 2008 [2].) Meanwhile, the definitional issue—what constitutes an "unnatural death"?—remains unresolved.

Reforms in Iatrogenic Death Investigations

To address this unsatisfactory situation, responding to a proposal from four medical specialty societies, the Ministry of Health, Labor & Welfare in 2005 launched a 5-year "Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths." The Model Project, now operating in eight of Japan's 47 prefectures including the most populous, is aimed at instituting impartial, high-quality peer review of possibly iatrogenic hospital deaths to provide accurate information to families and alleviate public concern about coverups of adverse medical events while in most cases avoiding police involvement.

When a patient dies in circumstances possibly related to medical management, the hospital, with the family's consent, may apply to the Model Project's regional office for an investigation. That office, on accepting a case, assembles a team of three physicians not connected with the hospital—a clinical pathologist, a forensic pathologist, and a specialist in the field of the patient's treatment—to conduct an autopsy. A separate evaluation committee reviews the patient's chart and the autopsy results, interviews hospital personnel, and prepares a report setting out the facts, a medical (not legal) evaluation of the course of care, and conclusions on how the adverse event could have been prevented. This report is shared with the hospital and family. A summary is made public with names of the patient, medical staff, hospital, and location masked [22].

The results of the Model Project so far are mixed but show promise. The level of police involvement has apparently diminished since the Project's launching. Frequently, a hospital initially notifies police of a patient's death, and after initial inquiries determine the case to be noncriminal, police refer the case to the Model Project [40]. The quality of case reviews conducted under Project auspices is likely higher than the reviews preceding the Project's establishment, and the level of transparency is undoubtedly enhanced. Evaluation committee recommendations for accident-preventive measures, if widely circulated, should contribute to medical safety advancements. The trustworthiness of evaluation committee reports may facilitate settlement of compensation claims, although this remains to be researched.

Cooperation from hospitals in participating regions has been uneven, and the number of cases handled by the Project has fallen considerably short of expectations. The Health Ministry planned for 200 cases annually when the Project was launched, but over the first 2¾ years, only 70 cases have been undertaken and only 57 reports completed [26]. Delays are common; mean duration from case submission to presentation of reports to families and hospitals is 10.1 months, compared with the originally contemplated deadline of 3 months [27]. Nevertheless, the Project's method of independent expert review of medical accidents is gaining traction, and in June 2008, the Health Ministry proposed legislation to expand some form of the enterprise to a national scale [25].

Discussion

The impact of law on Japanese medical practice was relatively minor for almost all of the 20th century. Japanese courts granted considerable deference to the medical profession, malpractice claims were few, and malpractice insurance premiums, uniform nationwide for physicians in private practice, were low.

In recent years, however, law has taken on a new importance for Japanese physicians. A social climate of greater transparency has formed the background for court decisions spurring adoption of a broader conception of informed consent. The quantity of malpractice claims has been rising and the number of attorneys is rapidly increasing, although neither claims nor attorneys approach levels prevalent in the United States. Public concern over a spate of highly publicized errors and coverups at well-known hospitals combined with efficiency improvements in courts' handling of medical cases has reinforced these trends. Of particular note, weaknesses in the medical profession's internal accountability structures have encouraged involvement of the criminal justice system in policing medical error, to the dismay of physicians and hospitals.

At the urging of medical specialty societies, the Health Ministry has undertaken a "model project" to enlist impartial medical specialists in the investigation and analysis of possibly iatrogenic deaths in Japanese hospitals. The project's aim is to regain public trust in the accuracy and honesty of the profession's evaluation of its members' mistakes and to provide guidance for safety improvements in the future. Legislation has been proposed to expand the project's scope and adapt its methods to a nationwide scale. This ongoing experiment is worthy of international attention because it may form a reference point for other nations' similar efforts.

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